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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,460

04/01/2002

Willem Johan Van Der Giessen

2005-1001

9285

466

7590

08/31/2009

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

08/31/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/089,460	Applicant(s) VAN DER GIESSEN ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment and response filed 02/18/2009.

The following rejection is maintained in this action:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 8- 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al (Journal of Vascular Surgery).

Schneider et al disclose vascular grafts on which a coating of heparin sulfate, laminin and collagen may be added (see abstract). This collagen is collagen type II and IV (see page 649, column 1, line 3). The composition may also contain nidogen (page 649, column 1, line 6) and bovine fibroblast growth factor (page 649, column 1, line 1). Nidogen and entactin are the same protein. Further, the reference specifically recited coating of the vascular grafts with extracellular matrix. Along with the components cited above, vitronectin and fibronectin are components of the extracellular matrix. Schneider further washes the extracellular matrix with a solution containing penicillin and

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streptomycin, adding antibiotics to the coating (see Materials and Methods, page 650). While the reference does not set out the percentages of each component, it is clear that all claimed components of the coating are present. As such, it would have been well within the skill of the ordinary practitioner to claim the instant intraluminal device by modifying the weight percentages of each through routine experimentation, and further, expect similar therapeutic results from the use of such a coating on an intraluminal device as set out by Schneider et al. Given that extracellular matrix already has these components present, applicant would need to show that the amounts set out in the claims would not be present in extracellular matrix, or that they are so unexpectedly different that they would teach away from the reference. As such, it is deemed that the instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the teachings of Schneider et al.

Response to Arguments

Applicant's arguments filed 02/18/2009 have been fully considered but they are not persuasive.

Applicant argues that Schneider et al makes no disclosure of the constituents of the present invention. However, as indicated in the previous response, the reference uses an ECM, the constituents of which are the same as those claimed herein.

Applicant further argues that the reference does not describe a synthetic coating, but rather a naturally produced coating. Applicant further argues that Schneider et al fails to set out the specific constituents in the percentages claimed. It must be noted

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however, that without a baseline measurement as to how much each constituent is present naturally, this argument lacks support. Further, whether natural or synthetic, the composition itself appears to be the same within a reasonable degree of modification.

Given that that the composition of the reference is natural, applicants argue that there is not motivation to vary the amounts of the constituents of the coatings. But quite the contrary, by showing that the composition and its constituents have therapeutic benefits, those of ordinary skill would have found it well within their skill to vary the amounts of these constituents in order to obtain a desired result.

Applicant further argues that there is no suggestion in Schneider et al to use isolated constituents, and in fact, the reference states that there are superior properties of the natural coating over the isolated constituents of ECM. However, this is not a teaching away, but a declaration of superior results. The statement shows that the isolated constituents also have some therapeutic activity which supports the rejection of record.

Applicant also argues that Schneider et al is concerned with improved adhesion and growth of EC's on synthetic graft material, not anti-thrombotic properties. However, this is viewed as an intended property. The claims are drawn to a composition, and as such, the reference discloses an ECM composition which reads on the claimed invention.

As such, it is deemed that the ordinary practitioner would have found it well within his or skill to claim the instant invention given the reference to Schneider et al as set forth in the rejection and statements above.

The following is a new rejection of the claims made in view of applicant's amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims now set out a "synthetic" composition which is not disclosed in the original specification. Preparation of a composition as recited at page 6, line 20 is not adequate support, since even natural compositions such as those used in bone growth,

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must first treat the natural composition to isolate the desired product. As such, this is considered new matter. Correction is requested.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz